

MAY 29 2002

K021384

Summary of Safety and Effectiveness
Liquichek™ Urine Toxicology Control Levels C1, C2, C3 and C4

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
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Contact Person

Ofelia Cachola
Regulatory Affairs Specialist
Telephone: (949) 598-1287

Date of Summary Preparation

May 1, 2002

2.0 **Device Identification**

Product Trade Name: Liquichek™ Urine Toxicology Control
Levels C1, C2, C3 and C4

Common Name: Drug Mixture Controls

Classifications: Class I

Product Code: 91DIF

Regulation Number: CFR 862.3280

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek™ Urine Toxicology Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K981590

4.0 **Description of Device**

Liquichek™ Urine Toxicology Control Levels C1, C2, C3 and C4 is prepared from human urine with added constituents of animal origin, drugs, drug metabolites, preservatives, and stabilizers.
The control is provided in liquid form for convenience.

This product contains 0.1% sodium azide as a preservative.

5.0 **Statement of Intended Use**

Liquichek™ Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

6.0 **Comparison of the new device with the Predicate Device**

The new Liquichek™ Urine Toxicology Control claims substantial equivalence to the Liquichek™ Urine Toxicology Control currently in commercial distribution (K981590). The new Liquichek™ Urine Toxicology Control has additional claims for Creatinine, pH, and Specific Gravity and the current product does not.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad (New Device) Liquichek™ Urine Toxicology Control	Bio Rad (New Device) Liquichek™ Urine Toxicology Control Predicate Device)
Similarities		
Intended Use	Liquichek™ Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.	Liquichek™ Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.
Levels	Same as predicate device.	<p>Level C1= Drugs added at Concentrations approximately 60% below confirmatory cutoffs or at LOQ.</p> <p>Level C2= Drugs added at concentrations 20-25% below confirmatory cutoffs.</p> <p>Level C3= Drugs added at concentrations above confirmatory cutoffs.</p>

		Level C4= Elevated confirmatory control.
Form	Liquid	Liquid
Matrix	Human urine	Human urine
Storage (Unopened)	2-8° C until expiration date	2-8° C until expiration date
Open Vial Claim	2-8° C for 30 days.	2-8° C for 30 days
Differences		
Analytes	Same analytes as the predicate device with the additional claims for Creatinine, pH and Specific Gravity.	D-Amphetamine, d-Methamphetamine, Amobarbital, Butalbital, Pentobarbital, Phenobarbital, Secobarbital, Alpha-Hydroxyalprazolam, Nordiazepam, Tetrahydrocannabinol (THC), Benzoyllecgonine, Ethanol, Lysergic Acid Diethylamide (LSD), Methadone, Methaqualone, Codeine, Morphine-3-β-D- Glucuronide, 6-Monoacetylmorphine, Phencyclidine and Propoxyphene

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Urine Toxicology Control Product claims are as follows:

7.1 Open vial: Once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C.

7.2 Shelf Life: 24 months when stored at 2-8°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, California 92618-2017

MAY 29 2002

Re: k021384
Trade/Device Name: Liquichek™ Urine Toxicology Control Levels C1, C2, C3, and C4
Regulation Number: 21 CFR § 862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: I
Product Code: DIF
Dated: May 1, 2002
Received: May 2, 2002

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

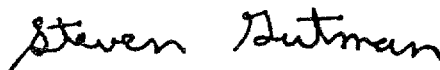
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

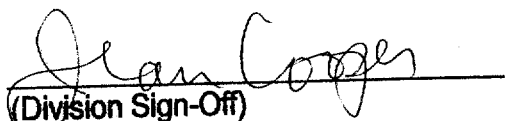
Enclosure

510 (k) Number (if known): K021384

Device Name: **Liquichek™ Urine Toxicology Control Levels C1, C2, C3, and C4**

Indications for Use:

A quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021384

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X or Over-the Counter use _____